



WARNING LETTER
ONPLDS-01-00

MAR 22 2000

Mr. Rory Mohny
General Manager
Nature's Way
10 Mountain Springs Parkway
Springville, Utah 84663

BY FACSIMILE AND CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dear Mr. Mohny:

This letter is in reference to your firm's marketing of the product "Pregnancy-6." The dietary supplement "Pregnancy-6" contains Black cohosh root, blessed thistle, false unicorn root, penny royal (flowering top), red raspberry leaves, and squaw vine (vine, leaf, fruit). The product is represented for use during the last 6 weeks of pregnancy. This letter is to advise you that this product violates the Federal Food, Drug, and Cosmetic Act (the FD&C Act) in several respects.

Black cohosh (*Cimicifuga racemosa* (L.) Nutt.), false unicorn root (*Chamaelirium luteum* (L.) A. Gray), penny royal (*Hedeoma pulegioides* (L.) Pers.), and blessed thistle (*Cnicus benedictus* (L.)) are listed as Class 2 herbs in the American Herbal Product Association's Botanical Safety Handbook (CRC Press, 1997). This classification is for herbs for which restrictions on specific uses apply, unless otherwise directed by an expert qualified in the use of the described substance. Each of the ingredients named above are classified as Class 2b, meaning they are not to be used during pregnancy. Another reference states that the ingredient *Rubus idaeus* L. or red raspberry leaves should be used during pregnancy only under experienced medical supervision because the nature of its effects on the uterus is unknown (Steven Foster, *An Illustrated Guide - 101 Medicinal Herbs*, Interweave Press, 1998).

These dietary ingredients cause a dietary supplement that contains them and that is represented for use by pregnant women to be adulterated under 21 U.S.C. 342(f)(1)(A) because the presence of these ingredients presents a significant or unreasonable risk of injury or illness under the conditions of use recommended or suggested in labeling; under 21 U.S.C. 342(f)(1)(D) because the product is a dietary supplement that is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) [21 U.S.C. 342(a)(1)] under the conditions of use recommended or suggested in the labeling of such dietary supplement; and under 21 U.S.C. 342(a)(1) because it contains a poisonous or deleterious substance that may render the supplement injurious to health.

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Moreover, your product is misbranded under 21 U.S.C. 343(a)(1) and 21 U.S.C. 321(n) because its labeling is false and misleading in that the labeling does not contain all information that is material in light of consequences that may result from the use of the product. For example, the labeling does not disclose representations made about the product and that the product contains ingredients that have been recommended not to be used by pregnant women or to be used by pregnant women only under the direct supervision of a qualified health care provider.

This letter is not intended to be an all-inclusive review of your firm's product and its labeling. It is your responsibility to assure that all products marketed by your firm are in compliance with the FD&C Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to make prompt corrections may result in enforcement action. This could include seizure of illegal products and injunctions against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter describing the specific steps you have taken to correct the violations and to prevent their recurrence. If corrective action cannot be completed within the 15 working days, state the reasons for the delay and the time within which the corrections will be completed.

Your reply should be addressed to John B. Foret, Director, Division of Compliance and Enforcement (HFS-810), Office of Nutritional Products, Labeling, and Dietary Supplements, Food and Drug Administration, 200 C St., SW, Washington, DC 20204.

Sincerely,

/s/

Christine J. Lewis, Ph.D.
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition